

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
74-R-0073

CUSTOMER NO.
1469

FORM APPROVED
OMB NO. 0579-0026

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)
UNIVERSITY OF TEXAS
301 UNIVERSITY BLVD
OFFICE OF THE ASSOCIATE DEAN FOR RESEARCH
GALVESTON, TX 77550
(409) 772-1275

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (sites)

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	27	0	27
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	18	2	743	763
7. Hamsters	0	219	281	742	1242
8. Rabbits	0	34	79	381	494
9. Non-Human Primates	0	0	7	0	7
10. Sheep	0	0	459	3	462
11. Pigs	0	0	201	0	201
12. Other Farm Animals					
Goats	0	0	6	0	6
13. Other Animals					
Gerbils	0	3	17	0	20
Ferrets	0	0	0	132	132
Cotton Rats	0	0	0	58	58

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).
ICIAL

(b)(6), (b)(7)c

(b)(6), (b)(7)c

9-23 (Oct 88), 1

DATE SIGNED
11/27/07
HEADQUARTERS

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Item Number	Procedures	Animal #s/Species
1	<p>The purpose of this study is to develop and characterize an aerosol or intranasal animal model in mice and guinea pigs for bacteria-like diseases for the investigation of antibiotics and vaccines against those diseases.. In order to establish small animal models, both mice and guinea pigs will be inoculated via intranasal or aerosol route and observed for clinical pathology of the disease. Since the initial experiments call for the use of agents to which C3H/HeN mice are resistant when these agents are administered by i.v. route, we need to develop and determine the full clinical course of the infection via the aerosol route using several mouse strains. Therefore we are requesting several strains (C3H/HeN, Balb/c and C57Bl/6) to develop our models. If none of the strains are useful in the development of aerosol models, we will utilize the established C3H/HeN models for future experiments. To fully characterize the models, the utilization of biosensors will be able to give a sensitive and accurate measurement of the animals' temperature during the course of the disease. The second aim of the project is to determine the effectiveness of therapeutic agents (vaccines, drugs and monoclonal antibodies) in mice and guinea pigs that have been inoculated by aerosol challenge and to fully characterize the protective response. The use of intervening therapies may alter the progression of the disease and adversely affect the study. We are using the guinea pigs to establish an aerosol model of infection for these diseases. One of the objectives of this protocol is to develop in depth and well characterized (molecular, immunological and histological) models in both mouse and guinea pigs. The use of pain and or distress relieving drugs would adversely affect the immunological and molecular markers that are major components of our experiments. They would also alter our observations of the clinical course of the disease.</p>	76 guinea pigs
2	<p>Several viruses are infectious in Syrian golden hamsters. Further, some strains but not others can cause a disease that is pathologically indistinguishable from fatal viral diseases in humans. The broad objective of the proposed work is to elucidate the pathogenesis of severe viral disease in hamsters. The specific objectives are to assess the effect of age of host at onset of infection, route of exposure, and inoculum dose on the course and outcome of infection. Samples of solid tissues and other biological specimens from the experimental animals will be tested for evidence of infection and markers of inflammation, and examined for histological and ultrastructural abnormalities. The results of this work are expected to advance our knowledge of the</p>	43 hamsters

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	<p>pathophysiological events that precede or coincide with the life-threatening pulmonary edema and then death or recovery from these severe viruses. In some experiments serum samples will be tested for virus-specific IgG; fresh-frozen samples of solid tissues will be tested for infectious virus, markers of oxidative stress, and various proinflammatory cytokines; formalin-fixed samples of solid tissues will be examined for histological abnormalities and, using an immunohistochemistry assay, viral antigen. Syrian golden hamsters are the only laboratory animal for studying the pathogenesis of pulmonary disease caused by viruses. The purpose of this study is to characterize the pathogenesis of viral infections in Syrian golden hamsters. The pathogenicity and virulence of certain viruses will be measured in juvenile and adult hamsters. Some of the experimental animals likely will develop severe pulmonary disease; however, death is not an endpoint. Note that the experimental animals will be closely monitored and – if severely dyspneic – euthanized by intraperitoneal injection of a lethal dose of sodium pentobarbital. Also note that the use of anesthetics, analgesics, sedatives, and anti-inflammatory compounds likely will alter the progression of the disease and/or preclude recognition of the disease state and that recognition and characterization of the disease state is essential to accurate interpretation of the laboratory assays done on blood and other tissue samples from the experimental animals. Accordingly, the experimental animals will not be treated with anesthetics, analgesics, sedatives, and anti-inflammatory compounds.</p>	
3	<p>The purpose of this study is to evaluate the vector competence of different ticks species to transmit bacteria-like infections, using guinea pigs as host to and also to perform immunological studies. This animal species is the most accurate and relevant model system for studying bacterial diseases and are therefore the animal model used in the study. Animals will either be needle injected with or tick-bite transmitted organisms. In order to carry out the study, the disease in the guinea pigs must be allowed to run its course with recognizable signs and symptoms. The use of intervening therapies that might alter the progression or recognition of the signs and symptoms of the infection in the animal model, including pharmacologic agents that do not have anti-inflammatory effects, would adversely affect the study.</p>	8 guinea pigs
4	<p>Guinea pigs and rabbits infected with these bacterial organisms do not exhibit clinical symptoms prior to death, which is sudden and unpredictable, based on the normal appearance of the animals. In addition, based on some studies using implanted telemetry, there are no indications of significant physiological changes. More specifically, there are no significant changes in temperature or blood chemistry during the course of the disease. Thus, there are no indications that would substantiate administering analgesics.</p> <p>There is evidence that analgesics and anesthetics can inhibit many drugs. Because we test so</p>	461 guinea pigs, 381 rabbits

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	<p>many varied drugs, vaccines, and other products for research purposes (in which the mechanism of action is unknown) that we can not know the potential interaction between these compounds and the analgesic agents.</p> <p>Our sponsors are trying to establish preclinical data and efficacy in these studies. Similar to clinical trials, human subjects would not receive analgesics unless they exhibited signs and symptoms of pain or distress. Thus, the Sponsors who are trying to mimic the disease and treatment in animal models would prefer not to have any other drug in the blood stream of their test subject that may interfere with the therapy that is being tested.</p> <p>Based on our years of working with guinea pigs and rabbits, we know that the addition of daily analgesic injections would evoke even more stress on the animals. Many of the compounds that we must test in animals also need to be given via the subcutaneous, intramuscular or intraperitoneal route via needles. Guinea pigs and rabbits similar to humans learn very quickly how to avoid the injections which lends to an increased risk for our personnel from needle sticks from animals that are infected with these bacterial organisms.</p>	
5	The goal of our experiments is to determine changes in pain thresholds to mechanical stimuli under nerve injury conditions. Accurate pain thresholds in test animals will not be obtainable if pain relief drug is administered.	3 sheep
6	<p>The purpose of this study is to examine the mechanisms of pathogenesis associated with parasite infections. Mice and hamsters are the most accurate and relevant model systems for studying cutaneous and visceral infestations and are therefore the animal models used in the study. Animals will be injected SQ with parasites. Control animals will receive a sham injection of PBS. To assess immunological and pathological changes during the course of infection, tissue samples will be collected from the skin, lymph node, spleen and liver, and will be used for examining signs and symptoms of parasite infection in the animal models, as well as cytokine/chemokine production in responses to parasite infection: cytokine gene expression, in-vitro T cell responses to parasite antigens, histology evaluation, and limiting dilution for parasite burdens in tissues. To prevent confounding effects on the animals' immune response to these parasites, we cannot use drugs that could alter the course of infection. Although skin lesions in cutaneous leishmaniasis patients do not accompany with pain, discomfort does occur when infected hosts have mucosal involvement, or enlarged spleen and liver. Therefore, it is anticipated that infected mice (for cutaneous disease models) or hamsters (for visceral disease models) will suffer mild-to-moderate pain or discomfort. It was recommended and approved by IACUC that leishmania infected animals will be listed under level E.</p>	6 hamsters
7	Following intravaginal or intrarectal virus inoculation animals begin to develop vesiculoulcerative skin lesions on the perineum 4-5 days post inoculation. The skin	

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	<p>disease reaches peak severity by 8-9 days post-inoculation and usually resolves spontaneously by 14-15 days post inoculation. During the acute infection the skin disease for each animal is quantified daily using a well-established 4 point severity scale. During the acute infection some animals develop urinary retention. In these animals the bladder is expressed daily in order to release the urine and minimize discomfort. During the primary infection animals may also experience hind-limb paralysis, as with the skin disease the vast majority of these animals recover spontaneously. However, all animals are observed daily. Animals in which hind-limb paralysis does not resolve within 4 days are euthanized by appropriate means. This is a neurotrophic virus thus we cannot use pharmacologic agents that alter the function of neuronal elements. Further the use of such agents which can alter the pathogenesis of disease can also affect the subsequent development of immune responses to infection. This in turn could affect the recurrent disease that is seen following resolution of the primary genital skin disease. During the recurrent phase of infection, animals develop spontaneous recurrent lesions. These lesions are episodic generally lasting 1-2 days and are not associated with any obvious signs of pain or distress in the animal. Historical data from our laboratory demonstrates that without intervention recurrent lesions are seen on ~10-20% of days with the frequency decreasing over time.</p>	60 guinea pigs
8	<p>These are experimental model systems being developed and utilized in a small number of laboratories including UTMB. There are no specific federal regulations, but these protocols have been approved for these studies by the NIH. The objectives of this project are to study development of virus diseases in animals and investigate strategies for treatment including the production and testing of candidate vaccines and other antiviral treatments. Two to four-day-old mice will be injected intracranially while infant hamsters, adult hamsters, and adult mice will be injected in the peritoneal cavity with a viral suspension to initiate infection. The pain and discomfort produced by virus infections consist of headaches, paralysis, and eventual death due to loss of ability to breathe or nurse. Animals will be observed daily for two weeks following inoculation or in some cases, animals may be retained for several weeks so that post-exposure blood can be collected to demonstrate viral infection by detection of flavivirus-specific sera. When signs of disease (hind limb paralysis and/or tremors, and/or severe fur ruffling) are detected at a level of severity that will result in death within 24 hours, the animals will be humanely euthanized. The use of intervening therapies might alter the natural progression, or recognition of the signs and symptoms, or the viral infection in</p>	

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	the animal model, including pharmacologic agents that do not have anti-inflammatory effects, would adversely affect the study and cannot be used.	159 hamsters
9	One of the purposes of this study is to test antiviral drugs for treatment of virus infection. Hamsters are one of the most accurate and relevant model systems for studying this viral disease and are the animal model used in the study. Animals will be injected with an antiviral drug followed by challenge with virus. Control animals will receive a sham injection followed by viral challenge. In order to test the effectiveness of antiviral drugs, measured by the difference in survival between the test and control animals, the viral infection must be allowed to run its course with recognizable signs or symptoms developing in the control animals and in any of the test animals not protected by the antiviral drugs. The use of intervening therapies that might alter the progression or recognition of the signs and symptoms of the viral infection in the animal model, including pharmacologic agents that do not have anti-inflammatory effects, would adversely affect the study.	67 hamsters
10	The purpose of this study is to investigate the therapeutic and/or prophylactic efficacy of several antiviral agents and viral-specific immune plasma alone or in combination against a highly contagious human respiratory disease for which there is no current effective interventions. The study will be conducted in a transgenic mouse model, which is the only animal model consistently revealing clinical and general illness and death when challenged with this virus. Golden Syrian hamsters will also be used as they can sustain a better virus replication and pathology than other reported models. Animals will be pretreated with various antiviral compounds followed by delayed intranasal challenge with infectious virus. The animals will be anesthetized for the inoculation procedure. Infected animals will be observed for a period up to 10 days and sacrificed when overtly ill, or at the end of the 14-day study. In order to test the effectiveness of the antiviral compounds measured by the difference in survival and/or clinical signs between the test and control animals, the viral infection must be allowed to run its course with recognizable signs or symptoms developing in the control animal and in any of the test animals not protected by the antiviral compound. The use of intervening therapies that might alter the progression or recognition of the signs and symptoms of the viral infection in the animal model, including pharmacologic agents that do not have anti-inflammatory effects, would adversely affect the study.	20 hamsters
11	The purpose of this study is to evaluate different immune cells and mechanisms for their ability to protect against certain viral infections. The viral infection itself can produce distress due to different factors; however, no procedure that is producing pain	4 hamsters

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	<p>will be performed without use of isoflurane. The virus can produce clinical symptoms including fever, anorexia, vomiting, muscle aches, malaise, encephalitis, and death. In general, these infections are not considered "painful" however, the virus potentially causes death. Prior to death animals develop paralysis of hind limbs and we will euthanize all paralyzed animals in our studies. Clinical signs associated with infection may include fever, anorexia, encephalitis, and death. The purpose of the present study is to evaluate several different pathways that are potentially involved in protection induced by the vaccine created in our laboratory. To do so the animals must be inoculated in an attempt to produce disease in the animal model. We need an animal model that not only becomes ill following inoculation but one that also demonstrates recognizable signs and symptoms of viral infection in order to test the hypothesis proposed. The use of anesthetics, analgesics, or sedatives may alter the progression of the disease or the ability to recognize the clinical symptoms associated with the disease process which would preclude us from recognizing the disease state and they can influence inflammatory response which would make it impossible for us to come up with conclusions that would be acceptable to the scientific community.</p>	
12	<p>The purpose of this study is to evaluate the efficacy of a virus-specific antiviral compound discovered during the initial SIBR Phase I work. The viral infection itself can produce distress due to different factors; however, no procedure that is producing pain will be performed without usage of isoflurane. The virus can produce clinical symptoms including fever, anorexia, vomiting, muscle aches, malaise and death. The use of pain relieving drugs is inappropriate for this study. To effectively test the antiviral compound against a lethal viral infection, it is imperative to limit the confounding variables of other therapeutic agents that may or may not mask clinical symptoms or have an effect on underlying tissue pathology.</p>	138 guinea pigs
13	<p>The purpose of this study is to evaluate the efficacy of antiviral compounds. The viral infection itself can produce distress due to different factors; however, no procedure that is producing pain will be performed without usage of isoflurane. The virus can produce clinical symptoms including fever, anorexia, vomiting, muscle aches, malaise, and death. In general, influenza viral infections are not considered "painful" although there may be considerable distress, and potentially death, associated with complications from those infections. Clinical signs associated with infection may include fever, anorexia, vomiting, muscle aches, and death. The purpose of the present study is to evaluate the efficacy of certain antiviral compounds against certain strains of influenza virus. To do so the animals must be inoculated in an attempt to produce disease in the animal model.</p>	132 ferrets

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	<p>We need an animal model that not only becomes ill following inoculation but one that also demonstrates recognizable signs and symptoms of viral infection in order to test the efficacy of three antiviral compounds. The use of anesthetics, analgesics, or sedatives may alter the progression of the disease or the ability to recognize the clinical symptoms associated with the disease process which would preclude us from recognizing the disease state and the effect of the antiviral compound on the disease process.</p>	
14	<p>Infection by these viruses may cause encephalitis and lymphoid depletion in mice, hamsters, and guinea pigs. Infection of some birds may also cause viscerotropic disease with diarrhea, as well as myocarditis and heart failure. All of these viruses may cause nonspecific symptoms including muscle aches, headaches and fever in these animals. Several different rodent and avian species are used because some develop higher titers of virus in the blood than others, depending on the virus strain and animal species used. We also study the ability of these viruses to infect and replicate in the bloodstream in some wild-caught animals without the involvement of mosquitoes. Four virus strains will be used to infect cotton rats for a viremia study and a survival study. A goal of these studies is to determine the level of viremia in animals after infection with viruses to assess their reservoir competence. It would be impossible to interpret our results if anti-inflammatory or any other analgesic drugs are used, because they might affect the viremia levels. Also, all analgesics interact in some way with the inflammatory response, which is integral part of the disease development, and some can affect the blood brain barrier, which could affect pathogenesis. i) Analgesics, such as non-steroidal analgesics (ibuprofen, acetyl salicylate, etc.) have anti-inflammatory effects that could affect virus replication and dissemination and/or affect thrombocytes that are important mediators in local inflammation (Breddin 2004) (Darling, Romero et al. 2004)(Hodges, Ireland et al. 2001). ii) Cerebral endothelial cells can release/express various products of arachidonic acid cascade with both vasoactive and pro-inflammatory properties, including prostaglandins, leukotrienes, and platelet-activating factor. These metabolites induce platelet and neutrophil activation and adhesion, changes in local cerebral blood flow and blood rheology, and increases in blood brain barrier permeability. iii) Inhibition of COX-1/2 as in the case of ibuprofen, aspirin and other non-steroidal anti-inflammatory drugs could modify the response of these cells after viral infection (Stanimirovic and Satoh 2000; Zhang, Smith et al. 2000). iv) Steroids such as cortisol affect the production of Leukotrienes and influence the blood brain barrier directly (Muruganandam, Smith et al. 2000). v). Some studies demonstrate that activation of opioid receptors within the central nervous system alters various</p>	<p>6 hamsters 33 cotton rats</p>

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	immune system parameters. Specifically, natural killer cell cytolytic activity and lymphocyte proliferative responses to mitogen appear to be modulated predominantly through central opioid receptors (Mellon and Bayer 1998; Mellon and Bayer 1998). This could influence the response to viral infection if additional opioids are used.	
15	<p>Infection by these viruses may cause encephalitis and lymphoid depletion in mice hamsters, and guinea pigs. All of these viruses may cause nonspecific symptoms including muscle aches, headaches and fever in these animals. The goal of some of one of our studies is to create vaccine candidates that induce an immune response sufficient to protect against lethal infection. Unfortunately, it is not possible to use moribund endpoints in this study because we need the data that will show if the vaccine will protect against lethal outcome and not against infection or disease only. It would be impossible to interpret our results and discuss protective mechanisms induced by these vaccines if additional anti-inflammatory or any other analgesic drugs are used. Also, all analgesics interact in some way with the inflammatory response, which is integral part of the disease development, and some can affect the blood brain barrier, which could affect pathogenesis. i) Analgesics, such as non-steroidal analgesics (ibuprofen, acetyl salicylate, etc.) have anti-inflammatory effects that could affect virus replication and dissemination and/or affect thrombocytes that are important mediators in local inflammation (Breddin 2004) (Darling, Romero et al. 2004)(Hodges, Ireland et al. 2001). ii) Cerebral endothelial cells can release/express various products of arachidonic acid cascade with both vasoactive and pro-inflammatory properties, including prostaglandins, leukotrienes, and platelet-activating factor. These metabolites induce platelet and neutrophil activation and adhesion, changes in local cerebral blood flow and blood rheology, and increases in blood brain barrier permeability. iii) Inhibition of COX-1/2 as in the case of ibuprofen, aspirin and other non-steroidal anti-inflammatory drugs could modify the response of these cells after viral infection (Stanimirovic and Satoh 2000; Zhang, Smith et al. 2000). iv) Steroids such as cortisol affect the production of Leukotrienes and influence the blood brain barrier directly (Muruganandam, Smith et al. 2000). v). Some studies demonstrated that activation of opioid receptors within the central nervous system alters various immune system parameters. Specifically, natural killer cell cytolytic activity and lymphocyte proliferative responses to mitogen appear to be modulated predominantly through central opioid receptors (Mellon and Bayer 1998; Mellon and Bayer 1998). This could influence the response to viral infection if additional opioids are used.</p>	8 hamsters
16	All of the animals in our studies will be inoculated with a virus that has the potential to	

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	<p>induce pain and/or distress following inoculation. Moreover, we must know how much virus we are giving to the test animals. Thus, it is necessary to titer each virus used and include relatively high doses in the titration. Knowing precisely how much virus is being given test animals is especially important in experiments assessing the protective efficacy of candidate antivirals and vaccines. It is important both in being able to get reproducible results in replicate experiments and in being able to determine if the antiviral or vaccine can prevent infection, illness, severe illness and mortality. Stated another way, the amount of challenge virus used in an experiment can significantly affect the apparent outcome of the experiment and the use of too little challenge virus can make a material appear safe and efficacious when it may not have been if more virus had been given the animals. We will not intentionally allow an animal to die. Instead, if an animal becomes moribund or exhibits marked stress or pain, it will be euthanized. No other drugs except what is being tested in the experiment can be given to the animals to reduce any pain or distress since this would make it impossible to evaluate the materials being tested. This is an initial study with this animal model and so we could not anticipate virus and vaccine interactions. It is important to clinically evaluate the animals without giving drugs that would alter the clinical signs or course of disease and therefore impact scoring efficacy of vaccines. Thus, minimization of pain and distress will be kept to a minimum by making frequent observations of the animal euthanizing any that appear to have untoward responses.</p>	25 cotton rats
17	<p>The pain that must not be alleviated will involve animals as a result of illness that will occur following infection with virus. These animals that develop illness, based on the results of more than 2 years of investigation, will be those that serve as controls (received placebo only) for assessing the efficacy of the vaccinated animals. Therefore, when the vaccinated and placebo treated animals are challenged, it will not be possible to assess efficacy of the vaccine unless the control animals are allowed to develop their natural course of illness. Interfering with the disease process to alleviate pain will adversely affect the outcome of the study. However, the animals will be euthanized with isoflurane to minimize pain and suffering once they show terminal signs and symptoms as described in section 4C1 of the protocol.</p>	376 hamsters
18	<p>The broad objective of the work is to elucidate the pathogenesis of severe viral disease in hamsters. The specific objectives are to assess the effect of age of host at onset of infection, route of exposure, and inoculum dose on the course and outcome of infection. Samples of solid tissues and other biological specimens from the experimental animals will be tested for evidence of infection and markers of inflammation, and examined for histological and ultrastructural abnormalities. The results of this work are expected to</p>	53 hamsters

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	<p>advance our knowledge of the pathophysiological events that precede or coincide with the life-threatening pulmonary edema and then death or recovery from severe disease. Syrian golden hamsters are the only laboratory animal for studying the pathogenesis of pulmonary disease caused by viruses. The purpose of this study is to characterize the pathogenesis of viral infections in Syrian golden hamsters. The pathogenicity and virulence of certain viruses will be measured in juvenile and adult hamsters. Some of the experimental animals likely will develop severe pulmonary disease; however, death is not an endpoint. Note that the experimental animals will be closely monitored and – if severely dyspneic – euthanized by intraperitoneal injection of a lethal dose of sodium pentobarbital. Also note that the use of anesthetics, analgesics, sedatives, and anti-inflammatory compounds likely will alter the progression of the disease and/or preclude recognition of the disease state and that recognition and characterization of the disease state is essential to accurate interpretation of the laboratory assays done on blood and other tissue samples from the experimental animals. Accordingly, the experimental animals will not be treated with anesthetics, analgesics, sedatives, and anti-inflammatory compounds</p>	
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2007 USDA Annual Report – Attachment
UTMB Galveston
Galveston, TX
74-R-073

Exceptions to Regulations and Standards
Approved by the Institutional Animal Care & Use Committee
University of Texas Medical Branch, Galveston, TX

Four hundred and fifty nine (459) sheep were housed in metabolic stanchions up to 4 weeks. The sheep were maintained in stanchions for 48 hours prior to surgery for psychological adaptation to this type of housing. The stanchions allow the sheep to stand or lie down in sternal recumbancy. The sheep were surgically instrumented with specialized equipment (chronic indwelling vascular catheters, etc.). These sheep are provided the most intensive care of any animals on campus. They are monitored 24 hours a day by research staff during the work week and observed minimally 4 times daily on weekends and holidays. In addition, they were observed daily, seven days a week by Animal Resources Center (ARC) veterinary and/or husbandry staff.

Seven (7) nonhuman primates (rhesus macaques) were used on a long term/chronic study. The monkeys were housed singly in two rooms. To prevent damage to the surgically implanted indwelling scientific devices in each animal, pair housing was not possible. Mutual grooming and the possibility of fighting between the monkeys could dislodge or expose the delicate medical instrumentation. Environmental enrichment is provided in the form of toys, puzzle feeders, and food treats. These nonhuman primates were also maintained in restraint chairs periodically, as required for the research study. During these sessions the monkeys receive treats/rewards and are not chaired longer than 4 hours in a 24 hour period.

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